

REMARKS

This paper is being filed in response to the Office Action dated January 14, 2004 that was issued in connection with the above-identified patent application. Applicants enclose herewith a Petition for Extension of Time pursuant to 37 C.F.R. §1.136(a) and the fee required under 37 C.F.R. §1.17(a)(1). Applicant also encloses herewith a Declaration under 37 C.F.R. § 1.132 ("Declaration"), a Supplemental Information Disclosure Statement (IDS), Form PTO-1449, and the fee required pursuant to 37 C.F.R. §§ 1.17(p) and 1.97(d)(2). Applicant respectfully requests reconsideration of the instant application in view of the amendments and remarks presented herein.

Claims 138-151 are pending in the instant application. Claims 138-140, 142, AND 148 have been amended. The amended claims are supported by the specification as originally filed, for example, at page 15, lines 5-22 and, therefore, do not constitute new matter. Claims 149-151 have been cancelled without prejudice. Claims 138-148 will be pending upon entry of the instant amendments.

As a preliminary matter, Applicant thanks the Examiner for her phone call on December 29, 2003 regarding the instant application. The Examiner indicated that claims drawn to the compositions set forth in Example II and other examples would be patentable. While Applicant appreciates the Examiner's suggestion, Applicant believes that such claims do not fully reflect the contribution to the art embodied in the instant application. Applicant, therefore, respectfully requests that Examiner consider the amendments and remarks presented herein as well as the attached Declaration.

Claim 139 has been objected to under 37 C.F.R. § 1.75(c) as allegedly failing to further limit the subject matter of the claim on which it depends. Applicant traverses this

objection and respectfully asserts that claim 139, as amended herein, complies with 37 C.F.R. § 1.75(c).

Claims Are Fully Supported by the Original Specification

Claims 138-150 have been rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one of ordinary skill in the art that Applicant was in possession of the claimed invention. The Examiner has noted that the claims 138-147 recite the phrase “free of alcohol.” The Examiner has alleged that the specification as filed does not provide support for this phrase. The Examiner has also alleged that the “specification as originally filed indirectly teaches that the alcohol(i.e. methanol) is used to make UD te,e has did not specifically mention of alcohol, the specification as originally filed does not exclude alcohol from the instant invention.” *See* Office Action dated 1/14/2004, p.3, lines 8-11. The Examiner has noted further that claims 148-150 recite a ratio (148), a percentage of the first material (149), and a percentage of the second material (150) and alleged that these figures are not supported by the application as filed.

Applicant traverses these rejections and asserts that the claims, as amended herein, are fully supported by the application as filed. Claims 149-150 have been cancelled without prejudice, thereby rendering this rejection moot as to these claims.

Applicant has amended the claims 138-147 to omit the phrase “free of alcohol.” However, Applicant does not acquiesce in the Examiner's allegation that the original specification lacks support for this phrase. Rather, Applicant has enclosed herewith a Declaration that obviates the need for this limitation. In addition, while Applicant is uncertain of the intended meaning of the foregoing quotation from the Office Action, Applicant respectfully

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submits that the methanol to which this sentence apparently refers is not added during the preparation of a solution of the invention. Instead, it is used only to elute serum bile acids from a sep-pak column after application of the serum sample thereto. *See* Example VI, p. 48, lines 5-8. The resulting eluate is substantially free of water. Therefore, it cannot be said that the instant application either directly or indirectly teaches preparation of aqueous solutions of the invention using methanol.

Claim 148 has been amended to recite a ratio of “about 25:1.” This ratio is fully supported by the application as filed at, for example, p. 23, lines 14-18. Specifically, the specification discloses that the minimal quantity of maltodextrin to ursodeoxycholic acid (UDCA) is as follows (deduced ratio shown in third column):

<u>Maltodextrin (g)</u>	<u>UDCA (mg)</u>	<u>Ratio</u>
5	200	25:1
25	1000	25:1
50	2000	25:1

See page 23, lines 14-18; *see also* the parent of this application, Serial No. 09/357,549 at page 17, lines 13-17 and page 24, lines 6-9. In addition, the specification states that determination of the minimal required quantity of starch conversion products depends on the ratio of carbohydrate to bile acid. *See* page 24, lines 13-16 (“The minimal required quantity of high molecular weight aqueous soluble starch conversion products is primarily determined by the absolute quantity of bile acids in the solution formulation rather than the concentration.”). One of ordinary skill in the art at the time the invention was made did not require further elaboration to understand that a maltodextrin to UDCA ratio of at least about 25:1 is required.

Claim 138-147 have been amended to recite “a first material selected from the group consisting of an aqueous soluble bile acid salt, a bile acid conjugated with an amine by an amide linkage, and combinations thereof.” Applicant asserts that this amendment is fully

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supported by the application as filed at, for example, Examples I, III to V, and VII, which each recite “soluble bile acid” or “soluble UDCA.” Soluble bile acids are defined in the specification at p. 20, line 12 *et seq.*

Therefore, since the instant claims are fully supported by the application as originally filed, Applicant respectfully requests withdrawal of these rejections.

Claims Are Not Anticipated by or Obvious over Satoshi

Claim 151 has been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Japanese Application No. 6215322 by Nakazawa Shinzo and Kuno Satoshi (abstract only; hereinafter “Satoshi”). Claim 151 has been cancelled without prejudice, thereby rendering this rejection moot as to this claim.

Claims 138-147 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Satoshi. The Examiner has alleged that Satoshi teaches an oral aqueous solution comprising bile acids such as UDCA and dextrans such as amyloextrin or D-glucose.

Applicant traverses this rejection and asserts that claims 138-148 are patentable over Satoshi since Satoshi does not enable preparation of clear solutions and fails to teach or suggest each and every limitation of the claims.

Claim 138 is not obvious over Satoshi since the Satoshi solution has been shown to consistently display substantially reduced stability compared to solutions of the invention. Applicant respectfully invites the Examiner's attention to the Declaration enclosed herewith. The Declaration presents the results of two independent experiments comparing the stability of the solutions of Satoshi and the instantly claimed solution. The data presented therein demonstrate that even if the solutions of Satoshi are clear initially, they do not remain clear over time. By contrast, the solutions of the present invention have been observed to remain clear for over

2 years. *See* p.31, line 2. In view of these surprising results, it cannot be said that the presently claimed solutions are obvious over Satoshi.

In an abundance of caution, in view of the previous citation of Satoshi against the instant application as § 102(b) art, Applicant additionally asserts that the Declaration enclosed herewith indicates that Satoshi is not available as prior art since it lacks an enabling disclosure. *See e.g.* MPEP § 2121.01, first paragraph. Therefore, claims 138-147 are not anticipated by Satoshi.

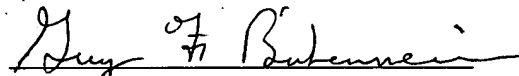
Finally, notwithstanding the foregoing arguments, claim 148 is not anticipated nor rendered obvious by Satoshi since Satoshi fails to teach or suggest a ratio of maltodextrin to UDCA of about 25:1. On the contrary, Satoshi expressly teaches that concentrations below 30:1 do not result in the formation of a clear solution. *See* Satoshi, professional English translation, p.5, paragraph [07]. Thus, claims 137-148 are not anticipated by nor obvious over Satoshi since Satoshi is not an enabling disclosure and Satoshi fails to teach each and every element of the claims. Accordingly, Applicants respectfully request withdrawal of these rejections.

The Commissioner is hereby authorized to charge the fee required under 37 C.F.R. § 1.17(a)(1) and § 1.17(p) to Deposit Account No. 02-4377. While Applicant does not believe that any additional fees are required, the Commissioner is hereby authorized to charge any required fees not otherwise enclosed herewith to Deposit Account No. 02-4377. Two copies of a Fee Transmittal sheet are enclosed.

Respectfully submitted,

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